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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,747	04/16/2004	W. Cary Dikeman	36433	1218

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EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,747

Applicant(s)

DIKEMAN ET AL.

Examiner

Laura C. Schell

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/27/04, 1/3/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gautsche (US Patent No. 6,458,104). Gautsche discloses a site securement device comprising a unitary body (Fig. 1) including multiple channels (50) of uniform shape and size, suitable for temporarily retaining a section of intravascular tubing in one or more of the channels (see abstract). Gautsche also discloses that the unitary body includes partitions (55) between the channels with flared end pieces. Gautsche further discloses that there are at least four channels and that at least two of the channels are separated by a space not adapted for temporarily retaining a section of the tubing (in between each "B" label, there is a wide, shallow trough that is a space not used for retaining the tubing).

Claims 7-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Dobkin (US Patent No. 5,735,821). Dobkin discloses a site securement device comprising a unitary body (Fig. 11) of uniform shape but varying size, suitable for temporarily retaining a section of intravascular tubing in one or more of the channels (see abstract). Dobkin further discloses that the body includes partitions between the channels (partitions in Fig. 11 are the projections between each channel (22)). Dobkin further

discloses that the partitions have flared end pieces, and the end pieces are rounded (each corner of the partition is rounded). Dobkin further discloses that there are at least four channels. Dobkin also discloses that the device includes an identical number of channels of each size (Fig. 9 shows a device with 3 channels, wherein each channel is a different size, therefore there are 3 different sizes for 3 different channels). Dobkin further discloses that the channels are configured to include outer channels of smaller size and inner channels of larger size (Fig. 9 discloses that the two outer channels (27 and 31) are smaller than the inner channel (22)). Dobkin also discloses that the channels are configured to include outer channels of larger size and inner channels of smaller size (Fig. 2 discloses that the two outer channels (25 and 27) are larger in size than the inner channel (26)). Dobkin further discloses that the at least two channels are separated by a space not adapted for temporarily retaining a section of the tubing (Fig. 11 discloses that the top of each projection (the projections between each channel) is a space that does not retain tubing).

Dobkin further discloses a site securement device (Fig. 4) with multiple channels (22a and 31a) of the uniform shape but varying size, suitable for temporarily retaining a section of intravascular tubing in one or more of the channels (see abstract) wherein no two channels are of the same size (each channel is a different size). Dobkin further discloses that the unitary body includes partitions (the projections between and on either side of the channels) with flared end pieces and wherein the end pieces are rounded (the corners of the projections are rounded, see 31b).

Claims 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bierman (US Patent No. 5,702,371). Bierman discloses a medical infusion apparatus (Fig. 15) comprising a catheter connected to a fluid supply tube (see first sentence of abstract) by a section of intravascular tubing (Fig. 15, 310), a site securement device (300) for anchoring the catheter and fluid supply tube to a patient (abstract, also see col. 23, line 48), said site securement device including a unitary body (304) having multiple uniform channels (328 and 330) for temporarily receiving a section of the intravascular tubing (col. 23, line 48) in one or more of the channels, and an adhesive pad (Fig. 19, 390; also see col. 29, lines 15-16) attached to said site securement device, said adhesive pad being attachable to the skin of a patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gautsche (US Patent No. 6,458,104) in view of Bierman (US Patent No. 6,290,676). Gautsche discloses the device substantially as claimed except for rounded end pieces and an adhesive pad. Bierman, however, discloses a site securement device (Figs. 9 and 10, 124) which comprises partitions between the channels with rounded end pieces (134). Bierman further discloses that the site securement device also comprises an adhesive pad for attachment to a patient (see abstract). Therefore it would have been

obvious to one of ordinary skill in the art at the time of the invention to have modified the site securement device of Gautsche with the rounded end pieces and adhesive pad, as taught by Bierman, in order to provide partitions without sharp corners in order to protect the tubing, and also to provide a device which could be attached to a patient's body, such that tubing could be interchanged without having to reattach the device and risk harming the patient's skin with repeated tape or other adhesive use.

Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobkin (US Patent No. 5,735,821) in view of Bierman (US Patent No. 5,702,371). Dobkin discloses the device substantially as claimed including a site securement device (Fig. 11), said site securement device including a unitary body having multiple uniformly shaped channels of varying sizes (22) for temporarily receiving a section of medical tubing (see abstract). Dobkin also discloses that the device includes an adhesive pad (28) for attaching to the skin of a patient. While Dobkin discloses that the device can be used for attaching various medical tubing (entire document), Dobkin does not disclose that the unitary body is used to receive intravascular tubing that is connected to both a catheter and fluid supply tube. Bierman, however, discloses a site securement device which is used to connect a fluid supply tube and catheter by a section of intravascular tubing (see abstract and col. 23, line 48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the site securement device of Dobkin, with the idea of using it to receive intravascular tubing that attaches a catheter and fluid supply tubing, as taught by Bierman, in order to provide another specific attachment use for the site securement device, wherein during

its use it provides a means of stability in relation to the patient, while connecting the various tubes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LCS

LCS

KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Sirmons